

claims as originally filed and that they do not constitute new matter. For example, specific support for polynucleotides comprising at least 50, 100, or 400 residues of the sequence of SEQ ID NO:808 or a complement thereof is provided on page 67, lines 3-12. It should be noted that the above amendments are not to be construed as acquiescence with regard to any of the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation, or continuation-in-part application.

Objection to the Abstract

The Action objects to the abstract of the disclosure as allegedly not reflecting the invention as elected. Applicants have amended the abstract to focus more specifically on the elected subject matter. Applicants submit that the abstract accurately reflects the elected invention and, therefore, respectfully request reconsideration and withdrawal of this objection.

Objection to the Claims

The Action objects to the claims as allegedly not reflecting the elected subject matter. Applicants have amended the claims to more clearly recite the elected subject matter and, therefore, request that this objection be withdrawn.

Rejection Under 35 U.S.C. § 101 and 35 U.S.C. § 112, First Paragraph

Claims 4-10 stand rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, on the alleged basis that the claimed invention lacks a patentable utility. More specifically, the Action alleges that the claims are not supported by a substantial utility and that the specification does not support the assertion that the polynucleotide sequence of SEQ ID NO:808 may be used for cancer diagnosis. Furthermore, the Action appears to suggest that a nucleic acid sequence shown to be overexpressed in lung tumor cells, as compared to normal lung cells, cannot be used in lung cancer diagnosis absent evidence that the polypeptide encoded by the nucleic acid is involved in cancer development.

Applicants respectfully traverse this rejection and submit that the invention possesses specific and substantial utility. Applicants submit that the polynucleotide sequence set

forth in SEQ ID NO:808 (L552S) is useful for the diagnosis of cancer, particularly lung cancer. Furthermore, Applicants submit that one of ordinary skill in the art would readily appreciate the usefulness of L552S polynucleotides for the detection of cancer, based upon the experimental results set forth in the instant specification. Applicants point out that L552S was identified by subtractive hybridization on the basis of its overexpression in human lung adenocarcinoma tissues derived from patients as compared to normal human tissues (Example 1). In addition, further analysis revealed that L552S mRNA was overexpressed in lung tumors as compared to all normal tissues tested, including normal lung tissue (page 156, line 15 through page 157, line 16). Applicants submit that this correlation between L552S mRNA overexpression and cancer clearly demonstrates that L552S polynucleotides may be used to detect cancer. Accordingly, Applicants submit that one of ordinary skill in the art would readily accept the assertion that L552S polynucleotides are useful for cancer diagnosis.

In addition, Applicants respectfully disagree with the Action's conclusion that the disclosed invention is merely an invitation for further research. Applicants submit that the experimental evidence and description provided in the specification support Applicant's assertion that L552S is useful for cancer diagnosis, and one of ordinary skill in the art would recognize the immediate, real-world usefulness of the invention for this purpose. Applicants also submit that the usefulness of L552S polynucleotides in cancer diagnosis resides in their overexpression in cancer tissue, and this usefulness does not require the overexpression of L552S polypeptides in cancer tissues or any functional involvement of L552S in cancer development. Applicants submit that one of ordinary skill in the art would understand that the expression levels and function of L552S polypeptides are irrelevant to the usefulness of L552S polynucleotides in cancer diagnosis, since the specification clearly demonstrates the correlation between L552S polynucleotide overexpression and cancer.

For the reasons stated above, Applicants submit that the invention clearly possesses a specific and substantial utility and respectfully request that the Examiner reconsider and withdraw this basis of rejection.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 4-10 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being vague and indefinite in reciting the terms "complement," "complementary," and "moderately stringent condition."

Applicants traverse this rejection and submit that these terms are clearly understood by one of ordinary skill in the art. Furthermore, "moderately stringent conditions" is defined in the instant specification on page 67, line 27, through page 68, line 3. Applicants submit that one of ordinary skill in the art would understand a "complement" or a "complementary" polynucleotide to comprise a complementary base at each position relative to the reference polynucleotide. Thus, Applicants submit that the claims satisfy the requirements of 35 U.S.C. § 112, second paragraph, and request that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 102(e)

Claims 4, 5, and 7-10 stand rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Patent No. 6,146,877 ("the '877 patent"). The Action specifically alleges that the '877 patent discloses a protein having at least fifteen residues of a protein encoded by SEQ ID NO:808 and having variations, such as additions, insertions, and substitutions. In addition, the Action asserts that the sequence disclosed in the '877 patent would be expected to hybridize to or be complementary to SEQ ID NO:808 and, therefore, anticipates the products of claims 7 and 8.

Applicants traverse this basis of rejection and submit that the '877 patent does not disclose a protein having at least fifteen residues of a protein encoded by SEQ ID NO:808. Rather, the '877 patent appears to disclose a protein having only five residues of a protein encoded by SEQ ID NO:808. Nonetheless, without acquiescing to this basis of rejection and solely to expedite prosecution, Applicants have cancelled the rejected claims and submitted new claims that essentially recite polynucleotides comprising SEQ ID NO:808, polynucleotides having at least 90% identity with SEQ ID NO:808 or a fragment thereof, and complements of these polynucleotides. Therefore, Applicants submit that this basis of rejection has been obviated and respectfully request reconsideration and withdrawal of the same.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version With Markings to Show Changes Made."

Applicants respectfully submit that all of the claims remaining in the application are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claims 4-10.